REMARKS

Reconsideration and further examination of this application is hereby requested. Claims 10-66 are currently pending in the application. Claims 15 and 54 have been amended. Claims 10, 11, and 58-66 have been withdrawn from consideration as being drawn to non-elected inventions.

A. APPLYING CLAIM LIMITATIONS TO THE DISCLOSURE

At page 2 of the Office Action of August 20, 2004, the PTO requires that each limitation or element of each of copied claims 12-57 be applied to the disclosure of the application. This requirement is subject to a one-month time limit, distinct from the three month shortened statutory period for the other issues raised in the Office Action. In reply to this requirement, applicant provides the following analysis concerning the claims and how they are supported by the disclosure.

A.1. APPLYING CLAIM 12 TO THE DISCLOSURE

Claim 12 recites the limitation

> circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of a muscle

This limitation is supported in the specification at page 11, para. 46, and at page 8, para. 36. These portions of the specification teach that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816 causing a maximum membrane

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potential without activation is achieved in the first phase of stimulation.

Claim 12 further recites the limitation

> circuitry for controlling the start time and/or the duration of the electric potential generated between said at least two points which is synchronized to heart activity

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that the memory circuit 840 allows certain control parameters, used by the control system 826 in controlling the operation of the pacemaker, to be programmably stored and modified, as required.

Claim 12 further recites the limitation

> said circuitry not operating at every beat of the heart

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.2. APPLYING CLAIM 13 TO THE DISCLOSURE

Claim 13 recites the limitation of an "implantable apparatus." This limitation is supported in the specification at

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page 12, para. 49; page 8, para. 36. This portion of the specification teaches an implantable pacer 810.

Claim 13 further recites the limitation of

> circuitry for causing a non-excitatory electric current to flow between at least two points located in the vicinity of a muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 13 further recites the limitation of

> circuitry for controlling the start time and/or duration of the electric current.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that the memory circuit 840 allows certain control parameters, used by the control system 826 in controlling the operation of the pacemaker, to be programmably stored and modified, as required.

Claim 13 further recites the limitation of

> wherein said circuitry for controlling does not operate at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert

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control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.3. APPLYING CLAIM 14 TO THE DISCLOSURE

Claim 14 recites the limitation of an

> Apparatus for selectively and reversibly reducing the oxygen consumption of an area of a muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 14 further recites the limitation of

> circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816 causing a maximum membrane potential without activation is

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achieved in the first phase of stimulation.

Claim 14 further recites the limitation of

> circuitry for controlling the start time and/or duration of the electric current flowing between said at least two points which is synchronized to heart activity.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that circuit 840 allows certain control parameters, used by the control system 826 in controlling the operation of the pacemaker, to be programmably stored and modified.

Claim 14 further recites the limitation of

> said circuitry not operating at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.4. APPLYING CLAIM 15 TO THE DISCLOSURE

Claim 15 recites the limitation of an

> Apparatus for reducing the contraction force of a muscle.

This aspect of the invention is disclosed at page 7, para. 35,

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describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 15 further recites the limitation of

> means for creating an electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 15 further recites the limitation of

> means for causing a non-excitatory DC electric current to flow between said at least two points, if desired.

This limitation is supported in the specification at page 11, para. 46, and at page 8, para. 36. This portion of the specification teaches that signal generator (*see* page. 7, para. 36) for causing "maximum membrane potential without activation is achieved in the first phase of stimulation". The pacemaker 810

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is coupled to a heart 812 by way of leads 814 and 816.

Claim 15 further recites the limitation of

> means for controlling the start time, duration and magnitude of the non-excitatory electric potential and/or of the non-excitatory electric current flowing between said at least two points.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that the memory circuit 840 allows certain control parameters, used by the control system 826 in controlling the operation of the pacemaker, to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

A.5. APPLYING CLAIM 16 TO THE DISCLOSURE

Claim 16 recites the limitation of

> means for creating an electric potential between at least a pair of electrodes in the vicinity of the muscle at at least two root locations.

This limitation is disclosed at page 2, para. 6, which discusses the "clumps and strands of specialized cardiac tissue," and at page 2, para. 7, which discloses placement of leads in the right atrium and the right ventricle. The description in these two succeeding paragraphs, taken as a whole, amounts to a disclosure of providing stimulation at at least two root locations.

Claim 16 further recites the limitation of

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> means for causing a non-excitatory DC electric current to flow between said at least two root locations when desired.

This limitation is supported in the specification at page 7, para. 36. This portion of the specification teaches the signal generator as causing the first phase of biphasic pulses.

Claim 16 further recites the limitation

> means for controlling the start time, duration and magnitude of the non-excitatory electric potential and/or of the non-excitatory electric current flowing between said at least two root locations.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that the memory circuit 840 allows certain control parameters, used by the control system 826 in controlling the operation of the pacemaker, to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

A.6. APPLYING CLAIM 17 TO THE DISCLOSURE

Claim 17 recites the limitation of

> A method for reducing the contraction force of a muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle

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activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 17 further recites the limitation of

> creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816 causing a maximum membrane potential without activation is achieved in the first phase of stimulation.

Claim 17 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that the memory circuit 840 allows certain control parameters, used by the control system 826 in controlling the operation of the pacemaker, to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular

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patient.

A.7. APPLYING CLAIM 18 TO THE DISCLOSURE

Claim 18 recites the limitation of

> A method for reducing the contraction force of a muscle

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 18 further recites the limitation of

> causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that a maximum membrane potential without activation is achieved in the first phase of stimulation. The pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 18 further recites the limitation

> controlling one or more of the parameters

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> consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that the memory circuit 840 allows certain control parameters, used by the control system 826 in controlling the operation of the pacemaker, to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

A.8. APPLYING CLAIM 19 TO THE DISCLOSURE

Claim 19 recites the limitation that "the muscle is a cardiac muscle." This limitation is supported in the specification at page 13, para. 52. This portion of the specification teaches that electrical stimulation is administered to the cardiac muscle.

A.9. APPLYING CLAIM 20 TO THE DISCLOSURE

Claim 20 recites the limitation that "the non-excitatory electric current is a DC current." This limitation is supported in the specification at page 7, para. 34. This portion of the specification teaches that the disclosed invention relates to the biphasic electrical stimulation of muscle tissue. Referring to the first phase 302 in Fig. 3, it is noted that this non-excitatory portion of the biphasic waveform is a DC current over

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a selected period of time.

A.10. APPLYING CLAIM 21 TO THE DISCLOSURE

Claim 21 recites the limitation of

> generating a complex signal by superimposing on the DC signal one or more waveforms of given frequency and amplitude.

This limitation is supported in the specification at page 6, para. 25. This portion of the specification teaches that the method and apparatus of the disclosed invention comprises a first and second stimulation phase, with each stimulation phase having a polarity, amplitude, shape and duration.

A.11. APPLYING CLAIM 22 TO THE DISCLOSURE

Claim 22 recites the limitation that

> the flow of the non-excitatory DC electric current is synchronized to heart activity.

This limitation is supported in the specification at page 13, para. 51. This portion of the specification teaches that the use of sensors makes the pacemaker rate-responsive, because the pacemaker adjusts the rate of pacing in a manner that tracks the physiological needs of the patient.

A.12. APPLYING CLAIM 23 TO THE DISCLOSURE

Claim 23 recites the limitation that "the non-excitatory DC electric current flows not at every beat of the heart." This aspect of the invention is disclosed at page 12, para. 48,

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describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.13. APPLYING CLAIM 24 TO THE DISCLOSURE

Claim 24 recites the limitation of a "method for performing heart treatment." This limitation is supported in the specification at pages 3-4, para. 13.

Claim 24 further recites the limitation of

> reducing the contraction force of a treated area of the cardiac muscle, by creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the

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specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 24 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points, thereby to obtain the desired reduction in muscle contraction at the treated heart area and thereafter performing treatment thereon.

This limitation is supported in the specification at pages 11-12, para. 47, which describes the signal generator circuitry.

A.14. APPLYING CLAIM 25 TO THE DISCLOSURE

Claim 25 recites the limitation of a "method for performing heart treatment." This limitation is supported in the specification at pages 3-4, para. 13.

Claim 25 further recites the limitation of

> reducing the contraction force of a treated area of the cardiac muscle, by causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone,

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reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 25 further recites the limitation

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points, thereby to obtain the desired reduction in muscle contraction at the treated heart area and thereafter performing treatment thereon.

This limitation is supported in the specification at pages 11-12, para. 47, which describes the signal generator circuitry.

A.15. APPLYING CLAIM 26 TO THE DISCLOSURE

Claim 26 recites the limitation that "the heart surgery is a bypass operation." The heart treatment method disclosed is not incompatible with use in conjunction with heart surgery. Electrical stimulation in combination with surgical intervention is well known in the art.

A.16. APPLYING CLAIM 27 TO THE DISCLOSURE

Claim 27 recites the limitation that "the heart surgery is a minimally invasive cardiac operation." The heart treatment

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method disclosed is not incompatible with use in conjunction with a minimally invasive cardiac procedure. Electrical stimulation in combination with surgical intervention is well known in the art.

A.17. APPLYING CLAIM 28 TO THE DISCLOSURE

Claim 28 recites the limitation of

> A method for promoting the healing of the cardiac muscle after myocardial infarct.

This limitation is supported in the specification at page 4, para. 15. This portion of the specification teaches that where nerve fibers have been damaged due to trauma or disease, muscle fibers in the regions supplied by the damaged nerve fiber tend to undergo atrophy and waste away. Through electrical stimulation one may maintain muscle tone, such that upon healing or regeneration of the nerve fiber, viable muscle tissue remains. Modified muscle contraction is obtained through the stimulation of the disclosed invention.

Claim 28 further recites the limitation of

> creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that a maximum membrane potential without activation is achieved in the first phase of stimulation. The pacemaker 810 is coupled to a

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heart 812 by way of leads 814 and 816.

Claim 28 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches controlling the operation of the pacemaker, via parameters that are to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

Claim 28 further recites the limitation that

> said electric potential being of an intensity and polarity suitable to obtain the desired reduction in muscle contraction at the affected heart area.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

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A.18. APPLYING CLAIM 29 TO THE DISCLOSURE

Claim 29 recites the limitation of

> A method for promoting the healing of the cardiac muscle after myocardial infarct.

This limitation is supported in the specification at page 4, para. 15. This portion of the specification teaches that where nerve fibers have been damaged due to trauma or disease, muscle fibers in the regions supplied by the damaged nerve fiber tend to undergo atrophy and waste away. Through Electrical stimulation one may maintain muscle tone, such that upon healing or regeneration of the nerve fiber, viable muscle tissue remains. Modified muscle contraction is obtained through the stimulation of the disclosed invention.

Claim 29 further recites the limitation of

> causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 14, para. 53. This portion of the specification teaches that the biphasic electrical stimulation is administered to the cardiac blood pool, that is, the blood entering and surrounding the heart. This enables cardiac stimulation without the necessity of placing electrical leads in intimate contact with cardiac tissue.

Claim 29 further recites the limitation of

> controlling one or more of the parameters

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> consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches controlling the operation of the pacemaker, via parameters that are to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

Claim 29 further recites the limitation that

> said electric current being of an intensity and polarity suitable to obtain the desired reduction in muscle contraction at the affected heart area.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

A.19. APPLYING CLAIM 30 TO THE DISCLOSURE

Claim 30 recites the limitation of

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> A method for selectively and reversibly reducing the oxygen consumption of an area of a muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 30 further recites the limitation of

> causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle

This limitation is supported in the specification at page 4, para. 13. This portion of the specification teaches that through the practice of the disclosed invention, one can enhance myocardial function through cardiac blood pool stimulation.

Claim 30 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.

This limitation is supported in the specification at page 12,

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para. 48. This portion of the specification teaches controlling the operation of the pacemaker, via parameters that are to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

Claim 30 further recites the limitation that

> said electric current being of an intensity and polarity suitable to obtain the desired reduction in oxygen consumption at the affected heart area.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

A.20. APPLYING CLAIM 31 TO THE DISCLOSURE

Claim 31 recites the limitation of

> A method for selectively and reversibly reducing the oxygen consumption of an area of a muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at

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page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 31 further recites the limitation of

> creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 4, para. 14. This portion of the specification teaches that the improved stimulation achieved through practice of the disclosed invention allows for cardiac stimulation without the necessity of placing electrical leads in intimate contact with cardiac tissue and the practice of the disclosed invention allows one to enhance myocardial function through cardiac blood pool stimulation.

Claim 31 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of said non-excitatory electric potential.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that controlling the operation of the pacemaker, via parameters that

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are to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

Claim 31 further recites the limitation of

> said electric potential being of an intensity and polarity suitable to obtain the desired reduction in oxygen consumption at the affected heart area.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

A.21. APPLYING CLAIM 32 TO THE DISCLOSURE

Claim 32 recites the limitation of

> A method for treating congenital or acquired hypertrophic cardiomyopathy

This limitation is supported in the specification at page 2, para. 7. This portion of the specification teaches that a patient suffering from a conduction disorder can be helped by an artificial pacemaker. Hypertrophic cardiomyopathy (or HCM) is

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often conceptualized as a muscular growth anomaly of the heart tissue, however, the course of the disease often manifests with conduction disorganization leading to a propensity for arrhythmia. Thus, HCM is properly treatable as a conduction disorder. Management of HCM by pacer implantation is well known in the art.

Claim 32 further recites the limitation of

> reducing the contraction force of the heart muscle by creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 32 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.

This limitation is supported in the specification at page 12,

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para. 48. This portion of the specification teaches controlling the operation of the pacemaker, via parameters that are to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

Claim 32 further recites the limitation of

> said electric potential being of an intensity and polarity suitable to obtain the desired reduction in muscle contraction.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

A.22. APPLYING CLAIM 33 TO THE DISCLOSURE

Claim 33 recites the limitation of

> A method for treating congenital or acquired hypertrophic cardiomyopathy.

This limitation is supported in the specification at page 2, para. 7. This portion of the specification teaches that a patient suffering from a conduction disorder can be helped by an

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artificial pacemaker. Hypertrophic cardiomyopathy (or HCM) is often conceptualized as a muscular growth anomaly of the heart tissue, however, the course of the disease often manifests with conduction disorganization leading to a propensity for arrhythmia. Thus, HCM is properly treatable as a conduction disorder. Management of HCM by pacer implantation is well known in the art.

Claim 33 further recites the limitation of

> reducing the contraction force of the heart muscle by causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the specification at page 11, para. 46, and at page 8, para. 36. These portions of the specification teach that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816 causing a maximum membrane potential without activation is achieved in the

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first phase of stimulation.

Claim 33 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches controlling the operation of the pacemaker, via parameters that are to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

Claim 33 further recites the limitation of

> said electric current being of an intensity and polarity suitable to obtain the desired reduction in muscle contraction.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

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A.23. APPLYING CLAIM 34 TO THE DISCLOSURE

Claim 34 recites the limitation of a "method for performing cardiac treatment." This limitation is supported in the specification at pgs. 3-4, para. 13.

Claim 34 further recites the limitation of

> reducing the contraction force of the area of the cardiac muscle to be treated, by creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 34 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two

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points, thereby to obtain the desired reduction in muscle contraction at the heart area to be treated

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the specification at page 12, para. 48. This portion of the specification teaches controlling the operation of the pacemaker, via parameters that are to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

Claim 34 further recites the limitation of "thereafter performing the treatment thereon." The heart treatment method disclosed is not incompatible with use in conjunction with other heart. Use of multiple treatment modes in combination with one another is well known in the art.

A.24. APPLYING CLAIM 35 TO THE DISCLOSURE

Claim 35 recites the limitation of a "method for performing

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cardiac treatment." This limitation is supported in the specification at pgs. 3-4, para. 13.

Claim 35 further recites the limitation of

> reducing the contraction force of the area of the cardiac muscle to be treated, by causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 35 further recites the limitation of

> controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points, thereby to obtain the desired reduction in muscle contraction at the heart area to be treated

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This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the specification at page 12, para. 48. This portion of the specification teaches controlling the operation of the pacemaker, via parameters that are to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

Claim 35 further recites the limitation of "thereafter performing the treatment thereon." The heart treatment method disclosed is not incompatible with use in conjunction with other heart. Use of multiple treatment modes in combination with one another is well known in the art.

A.25. APPLYING CLAIM 36 TO THE DISCLOSURE

Claim 36 recites the limitation that "the non-excitatory electric current is a DC current." This limitation is supported in the specification at page 7, para. 34. This portion of the

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specification teaches that the disclosed invention relates to the biphasic electrical stimulation of muscle tissue. Referring to the first phase 302 in Fig. 3, it is noted that this non-excitatory portion of the biphasic waveform is a DC current over a selected period of time.

A.26. APPLYING CLAIM 37 TO THE DISCLOSURE

Claim 37 recites the limitation of

> generating a complex signal by superimposing on the DC signal one or more waveforms of given frequency and amplitude.

This limitation is supported in the specification at page 6, para. 25. This portion of the specification teaches that the method of the disclosed invention comprises a first and second stimulation phase, with each stimulation phase having a polarity, amplitude, shape and duration.

A.27. APPLYING CLAIM 38 TO THE DISCLOSURE

Claim 38 recites the limitation that

> the flow of the non-excitatory DC electric current is synchronized to heart activity.

This limitation is supported in the specification at page 7, para. 34. This portion of the specification teaches that the disclosed invention relates to the biphasic electrical stimulation of muscle tissue. Referring to the first phase 302 in Fig. 3, it is noted that this non-excitatory portion of the biphasic waveform is a DC current over a brief interval, which

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repeats in synchrony with heart activity.

A.28. APPLYING CLAIM 39 TO THE DISCLOSURE

Claim 39 recites the limitation that

> the non-excitatory DC electric current flows not at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.29. APPLYING CLAIM 40 TO THE DISCLOSURE

Claim 40 recites the limitation that

> the cardiac muscle contractility is increased at locations other than the treated location.

This limitation is supported in the specification at pages 4-5, para. 15.

A.30. APPLYING CLAIM 41 TO THE DISCLOSURE

Claim 41 recites the limitation of

> A method for the interim treatment of a heart in need of reducing oxygen consumption.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These

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embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 41 further recites the limitation of

> reducing the contraction force of the heart muscle by creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, of an intensity and polarity suitable to obtain the desired reduction in muscle contraction at the treated heart area.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 41 further recites the limitation of

> thereby reducing the oxygen consumption of the heart.

This aspect of the invention is disclosed at page 7, para. 35,

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describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

A.31. APPLYING CLAIM 42 TO THE DISCLOSURE

Claim 42 recites the limitation of

> A method for the interim treatment of heart in need of reducing oxygen consumption.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 42 further recites the limitation of

> reducing the contraction force of a the heart muscle by causing a non-excitatory electric current to flow between at least two points

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> located in the vicinity of the muscle, of an intensity and polarity suitable to obtain the desired reduction in muscle contraction at the treated heart area.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the specification at page 11, para. 46. This portion of the specification teaches that causing a maximum membrane potential without activation is achieved in the first phase of stimulation through a pacemaker 810 coupled to a heart 812 by way of leads 814 and 816.

Claim 42 further recites the limitation

> thereby reducing the oxygen consumption of the heart.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle

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activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

A.32. APPLYING CLAIM 43 TO THE DISCLOSURE

Claim 43 recites the limitation that "the non-excitatory electric current is a DC current." This limitation is supported in the specification at page 7, para. 34. This portion of the specification teaches that the disclosed invention relates to the biphasic electrical stimulation of muscle tissue. Referring to the first phase 302 in Fig. 3, it is noted that this non-excitatory portion of the biphasic waveform is a DC current over a selected period of time.

A.33. APPLYING CLAIM 44 TO THE DISCLOSURE

Claim 44 recites the limitation of

> generating a complex signal by superimposing on the DC signal one or more waveforms of given frequency and amplitude.

This limitation is supported in the specification at page 6, para. 25. This portion of the specification teaches that the method of the disclosed invention comprises a first and second stimulation phase, with each stimulation phase having a polarity, amplitude, shape and duration.

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A.34. APPLYING CLAIM 45 TO THE DISCLOSURE

Claim 45 recites the limitation that

> the flow of the non-excitatory DC electric current is synchronized to heart activity.

This limitation is supported in the specification at page 7, para. 34. This portion of the specification teaches that the disclosed invention relates to the biphasic electrical stimulation of muscle tissue. Referring to the first phase 302 in Fig. 3, it is noted that this non-excitatory portion of the biphasic waveform is a DC current over a brief interval, which repeats in synchrony with heart activity.

A.35. APPLYING CLAIM 46 TO THE DISCLOSURE

Claim 46 recites the limitation that

> the non-excitatory DC electric current flows not at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.36. APPLYING CLAIM 47 TO THE DISCLOSURE

Claim 47 recites the limitation of

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> A method for reducing the contraction force of a muscle.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

Claim 47 further recites the limitation of

> providing means for creating an electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46, and at page 8, para. 36. This portion of the specification teaches that a maximum membrane potential without activation is achieved in the first phase of stimulation. The pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 47 further recites the limitation of

> providing means for causing a non-excitatory DC electric current to flow between said at least two point.

This limitation is supported in the specification at page 5,

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para. 24. This portion of the specification teaches administration of biphasic stimulation to the muscle tissue.

Claim 47 further recites the limitation of

> providing means for switching the current polarity between said at least two points.

This limitation is supported in the specification at page 7, paras. 35 36. This portion of the specification teaches that anodal first pulse phase is immediately followed by a cathodal second pulse phase.

Claim 47 further recites the limitation of

> providing means for controlling the start time, duration and magnitude of the electric current flowing between said at least two points.

This limitation is supported in the specification at page 12, para. 48. This portion of the specification teaches that circuit 840 allows certain control parameters, used by the control system 826 in controlling the operation of the pacemaker, to be programmably stored and modified, as required.

A. 37. APPLYING CLAIM 48 TO THE DISCLOSURE

Claim 48 recites the limitation of

> providing an electric potential between at least a pair of electrodes in the vicinity of the muscle at at least two root locations.

This limitation is disclosed at page 2, para. 6, which discusses the "clumps and strands of specialized cardiac tissue," and at

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page 2, para. 7, which discloses placement of leads in the right atrium and the right ventricle. The description in these two succeeding paragraphs, taken as a whole, amounts to a disclosure of providing stimulation at at least two root locations. This limitation is also supported in the specification at page 11, para. 46. This portion of the specification teaches that a maximum membrane potential without activation is achieved in the first phase of stimulation. The pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 48 further recites the limitation of

> causing a non-excitatory DC electric current to flow between said at least two contacting locations.

This limitation is supported in the specification at page 11, para. 46, and at page 8, para. 36. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816 causing a maximum membrane potential without activation is achieved in the first phase of stimulation.

Claim 48 further recites the limitation of

> providing means for switching the current polarity between said root locations.

This limitation is supported in the specification at page 7, paras. 35 36. This portion of the specification teaches that anodal first pulse phase is immediately followed by a cathodal

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second pulse phase.

Claim 48 further recites the limitation of

> controlling the start time, duration and magnitude of the electric current flowing between said at least two root locations, so as to obtain the desired reduction in muscle contraction.

This aspect of the invention is disclosed at page 7, para. 35, describing the embodiment illustrated in Fig. 2, as well as at page 9, para. 39, describing monophasic pacing. These embodiments provide reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption. This limitation is also supported in the specification at page 11, para. 46. This portion of the specification teaches controlling the operation of the pacemaker, via parameters to be programmably stored and modified, as required, in order to customize the pacer's operation to suit the needs of a particular patient.

A.38. APPLYING CLAIM 49 TO THE DISCLOSURE

Claim 49 recites the limitation of

> generating a complex signal by superimposing on the DC signal one or more waveforms of given frequency and amplitude.

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This limitation is supported in the specification at page 6, para. 25. This portion of the specification teaches that the method of the disclosed invention comprises a first and second stimulation phase, with each stimulation phase having a polarity, amplitude, shape and duration.

A.39. APPLYING CLAIM 50 TO THE DISCLOSURE

Claim 50 recites the limitation that

> the means for causing a non-excitatory DC electric current to flow, are synchronized to heart activity.

This limitation is supported in the specification at page 13, para. 51. This portion of the specification teaches that the use of sensors makes the pacemaker rate-responsive, because the pacemaker adjusts the rate of pacing in a manner that tracks the physiological needs of the patient.

A.40. APPLYING CLAIM 51 TO THE DISCLOSURE

Claim 51 recites the limitation that

> the means for causing a non-excitatory DC electric current to flow operate not at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to

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be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.41. APPLYING CLAIM 52 TO THE DISCLOSURE

Claim 52 recites the limitation of

> circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of the heart muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 52 further recites the limitation of

> circuitry for controlling the start time and/or duration of electric current flowing between said at least two points which is synchronized to heart activity.

This limitation is supported in the specification at page 13, para. 51. This portion of the specification teaches that the use of sensors makes the pacemaker rate-responsive, because the pacemaker adjusts the rate of pacing in a manner that tracks the physiological needs of the patient.

Claim 52 further recites the limitation

> wherein said circuitry for controlling does not operate at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In

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particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.42. APPLYING CLAIM 53 TO THE DISCLOSURE

Claim 53 recites the limitation of

> Apparatus for promoting the healing of the hibernated area of the cardiac muscle after myocardial infarct.

This limitation is supported in the specification at page 4, para. 15. This portion of the specification teaches that where nerve fibers have been damaged due to trauma or disease, muscle fibers in the regions supplied by the damaged nerve fiber tend to undergo atrophy and waste away. Through electrical stimulation one may maintain muscle tone, such that upon healing or regeneration of the nerve fiber, viable muscle tissue remains. Enhanced muscle contraction is obtained through the biphasic stimulation of the disclosed invention.

Claim 53 further recites the limitation of

> circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the

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pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 53 further recites the limitation of

> circuitry for controlling the start time and/or duration of the electric current flowing between said at least two points which is synchronized to heart activity.

This limitation is supported in the specification at page 13, para. 51. This portion of the specification teaches that the use of sensors makes the pacemaker rate-responsive, because the pacemaker adjusts the rate of pacing in a manner that tracks the physiological needs of the patient.

Claim 53 further recites the limitation of

> said circuitry not operating at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.43. APPLYING CLAIM 54 TO THE DISCLOSURE

Claim 54 recites the limitation of

> Apparatus for promoting the healing of an ischemic area of the cardiac muscle.

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This limitation is supported in the specification at page 4, para. 15. This portion of the specification teaches that where nerve fibers have been damaged due to trauma or disease, muscle fibers in the regions supplied by the damaged nerve fiber tend to undergo atrophy and waste away. Through electrical stimulation one may maintain muscle tone, such that upon healing or regeneration of the nerve fiber, viable muscle tissue remains. Enhanced muscle contraction is obtained through the biphasic stimulation of the disclosed invention.

Claim 54 further recites the limitation of

> circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 54 further recites the limitation of

> circuitry for controlling the start and/or duration of the electric current flowing between said at least two points which is synchronized to heart activity.

This limitation is supported in the specification at page 13, para. 51. This portion of the specification teaches that the use of sensors makes the pacemaker rate-responsive, because the pacemaker adjusts the rate of pacing in a manner that tracks the

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physiological needs of the patient.

Claim 54 further recites the limitation of

> said circuit not operating at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.44. APPLYING CLAIM 55 TO THE DISCLOSURE

Claim 55 recites the limitation of

> Apparatus for treating congenital or acquired hypertrophic cardiomyopathy.

This limitation is supported in the specification at page 2, para. 7. This portion of the specification teaches that a patient suffering from a conduction disorder can be helped by an artificial pacemaker. Hypertrophic cardiomyopathy (or HCM) is often conceptualized as a muscular growth anomaly of the heart tissue, however, the course of the disease often manifests with conduction disorganization leading to a propensity for arrhythmia. Thus, HCM is properly treatable as a conduction disorder. Management of HCM by pacer implantation is well known

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in the art.

Claim 55 further recites the limitation of

> circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 55 further recites the limitation of

> circuitry for controlling the start time and/or duration of the electric current flowing between said at least two points which is synchronized to heart activity.

This limitation is supported in the specification at page 13, para. 51. This portion of the specification teaches that the use of sensors makes the pacemaker rate-responsive, because the pacemaker adjusts the rate of pacing in a manner that tracks the physiological needs of the patient.

Claim 55 further recites the limitation of

> said current not operating at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert

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control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.45. APPLYING CLAIM 56 TO THE DISCLOSURE

Claim 56 recites the limitation of an

> Apparatus for aiding in performing cardiac treatment.

The disclosed device is suitable for use in cardiac treatment, which is merely an intended use of the apparatus.

Claim 56 further recites the limitation of

> circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle.

This limitation is supported in the specification at page 11, para. 46. This portion of the specification teaches that the pacemaker 810 is coupled to a heart 812 by way of leads 814 and 816.

Claim 56 further recites the limitation of

> circuitry for controlling the start time and/or duration of the electric current flowing between said at least two points which is synchronized to heart activity.

This limitation is supported in the specification at page 13, para. 51. This portion of the specification teaches that the use of sensors makes the pacemaker rate-responsive, because the pacemaker adjusts the rate of pacing in a manner that tracks the

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physiological needs of the patient.

Claim 56 further recites the limitation of

> said circuitry not operating at every beat of the heart.

This aspect of the invention is disclosed at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart.

A.46. APPLYING CLAIM 57 TO THE DISCLOSURE

Claim 57 recites the limitation that "the non-excitatory electric current is a DC current." This limitation is supported in the specification at page 7, para. 34. This portion of the specification teaches that the disclosed invention relates to the biphasic electrical stimulation of muscle tissue. Referring to the first phase 302 in Fig. 3, it is noted that this non-excitatory portion of the biphasic waveform is a DC current over a selected period of time.

Claim 57 further recites the limitation

> signal generation circuitry for superimposing on the DC signal one or more waveforms of given frequency and amplitude, thereby to generate a complex signal.

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This limitation is supported in the specification at page 6, para. 25. This portion of the specification teaches that the method of the disclosed invention comprises a first and second stimulation phase, with each stimulation phase having a polarity, amplitude, shape and duration.

B. THE WRITTEN DESCRIPTION REQUIREMENT

Claims 12-57 have been rejected under 35 U.S.C. § 112, ¶ 1st, as failing to comply with the written description requirement. This rejection is respectfully traversed based on the following arguments.

B.1. THE "EVERY BEAT OF THE HEART" ISSUE

This rejection calls into question the support in the original disclosure for the limitation that pulses are delivered "not at every beat of the heart."

The Examiner's attention is respectfully directed to the disclosure at page 12, para. 48, describing the control parameters for delivering pulses. In particular it is disclosed that an "atrial escape interval" is programmed. This parameter permits the heart to re-assert control of pacing itself and thereby cause delivery of pulses to be suppressed. In this way, pulse delivery would occur not at every beat of the heart. Persons having ordinary skill in the art would have understood this functionality of an atrial escape interval in a programmed

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pacer.

For this reason, Applicant respectfully submits that this aspect of the claimed invention is supported by the disclosure as originally filed.

B.2. THE "OXYGEN CONSUMPTION" ISSUE

This rejection also calls into question the support in the original disclosure for the limitation regarding reducing oxygen consumption.

The Examiner's attention is respectfully directed to the disclosure at page 7, para. 35, describing the embodiment illustrated in Fig. 2. Additionally, please refer to page 9, para. 39, describing monophasic pacing. Although these are not preferred embodiments, they are disclosed as providing reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

For this reason, Applicant respectfully submits that this aspect of the claimed invention is supported by the disclosure as originally filed.

B.3. THE "CONTRACTION FORCE" ISSUE

This rejection also calls into question the support in the

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original disclosure for the limitation regarding reducing contraction force.

The Examiner's attention is respectfully directed to the disclosure at page 7, para. 35, describing the embodiment illustrated in Fig. 2. Additionally, please refer to page 9, para. 39, describing monophasic pacing. Although these are not preferred embodiments, they are disclosed as providing reduced results for causing muscle activation. Providing the subthreshold anodal pulse alone, reversing the order of the polarities (per Fig. 2), or reducing the amplitude and duration of the cathodal pulse so as to be subthreshold accomplishes reduced contraction and oxygen consumption.

For this reason, Applicant respectfully submits that this aspect of the claimed invention is supported by the disclosure as originally filed.

B.4. THE "ROOT LOCATIONS" ISSUE

This rejection also calls into question the support in the original disclosure for the limitation regarding providing stimulation at at least two root locations.

The Examiner's attention is respectfully directed to the disclosure at page 2, para. 6, which discusses the "clumps and strands of specialized cardiac tissue," and at page 2, para. 7, which discloses placement of leads in the right atrium and the

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right ventricle. The description in these two succeeding paragraphs, taken as a whole, amounts to a disclosure of providing stimulation at at least two root locations.

For this reason, Applicant respectfully submits that this aspect of the claimed invention is supported by the disclosure as originally filed.

B.5. THE "HEALING AFTER INFARCT" ISSUE

This rejection also calls into question the support in the original disclosure for the limitation of promoting healing after myocardial infarction.

The Examiner contends that the disclosure concerning "trauma or disease" (refer to page 4, para. 15) does not include the specific problem of "infarct." However, infarct is a trauma. Although myocardial infarct is not the only type of heart trauma, it is so prevalent as to be the first type of heart trauma that would spring to the mind of a person having skill in the cardiology art.

For this reason, Applicant respectfully submits that this aspect of the claimed invention is supported by the disclosure as originally filed.

B.6. THE "HYPERTROPHIC CARDIOMYOPATHY" ISSUE

This rejection also calls into question the support in the original disclosure for the limitation of treating hypertrophic

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cardiomyopathy.

This limitation is supported in the specification at page 2, para. 7. This portion of the specification teaches that a patient suffering from a conduction disorder can be helped by an artificial pacemaker. Hypertrophic cardiomyopathy (or HCM) is often conceptualized as a muscular growth anomaly of the heart tissue, however, the course of the disease often manifests with conduction disorganization leading to a propensity for arrhythmia. Thus, HCM is properly treatable as a conduction disorder. Management of HCM by pacer implantation is well known in the art.

For this reason, Applicant respectfully submits that this aspect of the claimed invention is supported by the disclosure as originally filed.

B.7. THE "HEAL ISCHEMIC AREA" ISSUE

This rejection also calls into question the support in the original disclosure for the limitation of healing an ischemic area.

The Examiner contends that the disclosure concerning "trauma or disease" (refer to page 4, para. 15) does not include the specific problem of "ischemia." However, ischemia <u>is</u> disease. In fact, ischemia is a very common aspect of heart disease.

For this reason, Applicant respectfully submits that this

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aspect of the claimed invention is supported by the disclosure as originally filed.

B.8. THE "ABLATION" ISSUE

This rejection also calls into question the support in the original disclosure for the limitation of ablation.

This is simply a misunderstanding. None of the pending claims recite a limitation concerning "ablation." Applicant's mention in the R. 607 filing of "ablation" was in error. Claim 56 recites "treatment," not "ablation." *See* the preliminary amendment filed May 15, 2002.

For this reason, Applicant respectfully submits that this is a non-issue caused by a miscommunication. The undersigned accepts responsibility for this miscommunication and regrets any inconvenience it may have caused.

C. CLAIM OBJECTION

Claim 15 has been objected to as containing a grammatical error. The grammatical informality noted by the Examiner has been corrected by the present amendment. Additionally, claim 54 has been amended to correct an obvious spelling error.

D. CLOSING

For the above reasons, Applicant respectfully submits that claims 12-57 are allowable. Further, Applicant respectfully

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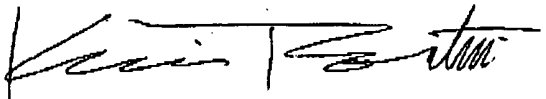
submits that institution of interference with U.S. patent no. 6,233,484 is appropriate.

The Director of the U.S. Patent & Trademark Office is authorized to charge any necessary fees, and conversely, deposit any credit balance, to Deposit Account No. 18-1579.

Respectfully submitted,
ROBERTS ABOKHAIR & MARDULA, LLC



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